

**Clinical Experience (Volume) Requirements for Adult Transplants that are
Performed in Primarily Pediatric Transplant Centers**

Update: October 29, 2007

Transplant programs that perform transplants on primarily pediatric patients (i.e., 50% or more of the patients are under age 18) but who also transplant some adult patients age 18 or over must apply separately under the new regulations for both the adult and pediatric transplant programs.

Under the new Medicare Conditions of Participation (CoP), certain types of adult transplant programs are subject to clinical experience (volume) requirements for both initial approval and re-approval under the CoPs. Transplant programs that perform primarily pediatric transplants will be exempt from the clinical experience requirements for their adult program for *initial* approval under the Conditions of Participation. This exemption is outlined in 42 CFR §482.76 (c)(3) of the regulation which states that “a center that performs 50% or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.” The exemption in the regulation applies *only* to the initial approval under the CoPs; it does not extend the exemption to the *re-approval* process which requires that those adult transplant programs subject to clinical experience requirement will conduct an average of 10 transplants per year over the re-approval period.

For any questions related to this issue, please contact Karen Tritz at (410) 786-8021 or karen.tritz@cms.hhs.gov.